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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,059	07/10/2006	Wolfgang Greb	06-206	5376

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EXAMINER

NWAONICHA, CHUKWUMA O

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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01/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,059	Applicant(s) GREB ET AL.	
	Examiner Chukwuma O. Nwaonicha	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Current Status

1. This action is responsive to Applicants' communication of 10 July 2006.
2. Claims 14-27 are pending in the instant application.
3. This Application is a 371 of PCT/DE05/00095 01/24/2005

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 20 and 21 are indefinite because the phrase "preferably 1 to 6" renders the claims indefinite. The metes and bounds of the claims are unclear. Correction is required.

Claim 18 is indefinite because the words or agents "therapeutic cancer agents, virustatic agents, antibiotics, antimycotic agents, anti-inflammatory agents"

renders the claims indefinite. It is not clear what antibiotic or agents applicants are claiming. Applicants have to be specific. Correction is required.

Claim 19 is indefinite because the words or phrases "liposomes, nanoparticles, nanospheres, nanocapsules, micelles, or polymer systems" renders the claims indefinite. It is not clear what applicants are claiming. Applicants have to be specific. Correction is required.

Claims 20, 21, 22, 26 and 27 are indefinite because the phrase "uronic acid derivative, a derivative thereof and any individual active substance or combination of active substances" renders the claims indefinite. It is not clear what derivative or active substance applicants are claiming. Clarification is required.

Claim 23 is indefinite because the phrase "ceramide in their natural, semi-synthetic or synthetic forms". It is not clear what applicants are claiming. Clarification is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for "treating human diseases and animal diseases" with the composition of the compound of claim 1.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

In the instant case, the claims cover "treating human diseases and animal diseases" with the composition of the compound of claim 1. Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to use this invention without undue experimentation. See M.P.E.P. 2164.01. Given the scope of the claims, it does not, because "treating human diseases and animal diseases" with the composition of the compound of claim 1. is speculative.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a)). However, the instant case goes

beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention from the claim to "treating human diseases and animal diseases" with the composition of the compound of claim 1.

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, **claim 25** is *prima facie* non-enabled for their full scope.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (*In re Wands*, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

- (1) **Nature of the invention.** As indicated above, the invention is drawn to "treating human diseases and animal diseases" with the composition of the compound of claim 1.
- (2) **Breadth of the Claims.** The claim is extremely broad. In particular, **claim 25** that read on specifically "treating human diseases and animal diseases" with the composition of the compound of claim 1. Applicants have failed to exactly show how to "treating human diseases and animal diseases" with the composition of the compound of claim 1.

(5) **Amount of Guidance Provided.** Applicants have provided no guidance for “treating human diseases and animal diseases” with the composition of the compound of claim 1. However, when considering that the claims read on “treating human diseases and animal diseases” with the composition of the compound of claim 1. It becomes critical to know how long does one administers the said composition. This is critical to the practice of the invention and therefore should adequately be disclosed.

(7) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. This is a new field with no known success to “treating human diseases and animal diseases” with the composition of the compound of claim 1.

(8) **Amount of Experimentation Necessary.** A great deal of experimentation is required. In lieu of the fact that no animal models exist which can reasonably suggest successful “treating human diseases and animal diseases” with the composition of the compound of claim 1. it will be necessary for an ordinary skilled artisan to have clinical data in order to practice the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on 571-272-0871.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chukwuma O. Nwaonicha, Ph.D.
Patent Examiner
Art Unit: 1621

**J. PARSA
PRIMARY EXAMINER**



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